

## RECEIVED NOV 2 2 2002

**TECHNOLOGY CENTER R3700** 

Please enter the following substitute paragraph for the specification at page 2, line 1, as follows:

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The stent of the present invention generally includes a plurality of cylindrical elements that are interconnected to form the stent. The stent typically is mounted on a balloon catheter if it is balloon expandable, or else it is mounted on a catheter without a balloon if it is self-expanding.

Please enter the following substitute paragraph for the specification at page 5, line 19 as follows:

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FIG. 11 is a cross-sectional view of the stent strut.

Please enter the following substitute paragraph for the specification at page 5, line 20 as follows:

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FIG. 12 is a cross-sectional view of a wider stent strut.

Please enter the following substitute paragraph for the specification at page 10, line 20 as follows:

Referring to FIGS. 5-7, the stent of the invention can be described as having cylindrical rings formed of U-shaped portions 90, Y-shaped portions 92, and W-shaped portions 94. Again, while the stent is generally laser cut from a solid tube and it typically has no discrete parts, for ease of identification the stent of the invention also can be referred to as having U-, Y-, and W-shaped portions. The U-shaped portions have no supporting structure attached thereto. The Y-shaped portions, at their base, or apex, have arm 68 extending therefrom and attached to undulating link 54. The W portion has at its base or curve portion arm 69 which attaches at the other end of the undulating link. The length of the arms attaching the links to the rings can vary. Importantly, the arms should be sized in conjunction with the undulating link so that the link is properly positioned in the W-shaped portion. Preferably, undulating link 54 is contained within W-shaped portion 94, which should be wide enough to accommodate the undulating link when the stent is crimped so that no portion of the undulating link and the W-portion overlap. Preferably, the undulating link and the W-shaped portion are in the same cylindrical plane 50 as defined by the cylindrical outer wall surface 52 and the cylindrical inner wall surface 53.

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Please enter the following substitute paragraph for the specification at page 11, line 17 as follows:

In one aspect of the invention, the stent is formed so that the struts 98 (FIG. 13) have variable thickness (not shown) along the stent length. As one example, it is contemplated that struts 104 at the ends of the stent may be radially thicker than the struts 106 in the center of the stent for purposes for radiopacity and to counter balloon expansion. When the balloon first inflates, the balloon ends have a tendency to inflate at a faster rate than the balloon center, however, with thicker struts at the stent ends the balloon, and hence the stent, will expand more uniformly.

Please enter the following substitute paragraph for the specification at page 12, line 20 as follows:

FIGS. 17 and 18 are conceptually similar to FIGS. 15 and 16. The stent 310 comprises a plurality of cylindrical rings 340 connected by links 354. Apertures 380 are elliptically shaped with the major axis of the ellipse running perpendicular to the stent's longitudinal axis. In other words, the long part of the ellipse 382 is perpendicular to the longitudinal axis, and the short elliptical part 384 is parallel. The link 354 also includes tapered portion 385 and radius portion 387. The structural portion surrounding the elliptical aperture 380 responds to stress in much the same way as the rectangular structure in FIG 16. As the ellipse is stretched in tension it becomes more circular and less elliptical. As the ellipse is placed in compression, it becomes more elliptical,

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approaching the shape of a thin rectangle, a slit, or even two separate rounded apertures separated by a contact point.

Please enter the following substitute paragraph for the specification at page 14, line 11 as follows:

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The tubing may be made of suitable biocompatible material such as stainless steel or another metal alloy. The stainless steel tube may be Alloy type: 316L SS, Special Chemistry per ASTM F138-92 or ASTM F139-92 grade 2. Special Chemistry of type 316L per ASTM F138-92 or ASTM F139-92 Stainless Steel for Surgical Implants in weight percent.

| Carbon (C)      | 0.03% max.   |
|-----------------|--------------|
| Manganese (Mn)  | 2.00% max.   |
| Phosphorous (P) | 0.025% max.  |
| Sulphur (S)     | 0.010% max.  |
| Silicon (Si)    | 0.75% max.   |
| Chromium (Cr)   | 17.00-19.00% |
| Nickel (Ni)     | 13.00-15.50% |
| Molybdenum (Mo) | 2.00-3.00%   |

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Nitrogen (N)

0.10% max.

Copper (Cu)

0.50% max.

Iron (Fe)

Balance

The stent diameter is very small, so the tubing from which it is made must necessarily also have a small diameter. Typically the stent has an outer diameter on the order of about 0.06 inch (1.524 mm) in the unexpanded condition, the same outer diameter of the tubing from which it is made, and can be expanded to an outer diameter of 0.1 inch (2.54 mm) or more. The wall thickness of the tubing is about 0.003 inch (0.0762 mm).

Please enter the following substitute paragraph for the specification at page 15, line 15 as follows:

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Cutting a fine structure (0.0035 inches or 0.0889 mm web width) requires minimal heat input and the ability to manipulate the tube with precision. It is also necessary to support the tube yet not allow the stent structure to distort during the cutting operation. In order to successfully achieve the desired end results, the entire system must be configured very carefully. The tubes are made typically of stainless steel with an outside diameter of 0.060 to 0.066 inches (1.524-1.676 mm) and a wall thickness of 0.002 to 0.004 inches (0.0508-0.1016 mm). These tubes are fixtured under a laser and positioned utilizing

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CNC equipment to generate a very intricate and precise pattern. Due to the thin wall and the small geometry of the stent pattern (0.0035 inches or 0.0889 mm typical web width), it is necessary to have very precise control of the laser, its power level, the focused spot size, and the precise positioning of the laser cutting path.

Please enter the following substitute paragraph for the specification at page 16, line 26, through page 17 line 12 as follows:

In addition to the laser and the CNC positioning equipment, the optical delivery system includes a beam expander to increase the laser beam diameter, a circular polarizer, typically in the form of a quarter wave plate, to eliminate polarization effects in metal cutting, provisions for a spatial filter, a binocular viewing head and focusing lens, and a coaxial gas jet that provides for the introduction of a gas stream that surrounds the focused beam and is directed along the beam axis. The coaxial gas jet nozzle (0.018 inches or 0.4572 mm I.D.) is centered around the focused beam with approximately 0.010 inches (0.254 mm) between the tip of the nozzle and the tubing. The jet is pressurized with oxygen at 20 psi and is directed at the tube with the focused laser beam exiting the tip of the nozzle (0.018 inches or 0.4572 mm dia.). The oxygen reacts with the metal to assist in the cutting process very similar to oxyacetylene cutting. The focused laser beam acts as an ignition source and controls the reaction of the oxygen with the metal. In this

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manner, it is possible to cut the material with a very fine kerf with precision. In order to prevent burning by the beam and/or molten slag on the far wall of the tube I.D., a stainless steel mandrel (approx. 0.034 inches or 0.8636 mm dia.) is placed inside the tube and is allowed to roll on the bottom of the tube as the pattern is cut. This acts as a beam/debris block protecting the far wall I.D.

Please enter the following substitute paragraph for the specification at page 18, line 4 as follows:

The cutting process utilizing oxygen with the finely focused green beam results in a very narrow kerf (approx. 0.0005 inches or 0.0127 mm) with the molten slag resolidifying along the cut. This traps the cut out scrap of the pattern requiring further processing. In order to remove the slag debris from the cut allowing the scrap to be removed from the remaining stent pattern, it is necessary to soak the cut tube in a solution of HCL for approximately 8 minutes at a temperature of approximately 55° C (131° F). Before it is soaked, the tube is placed in a bath of alcohol/water solution and ultrasonically cleaned for approximately 1 minute to remove the loose debris left from the cutting operation. After soaking, the tube is then ultrasonically cleaned in the heated HCL for 1-4 minutes depending upon the wall thickness. To prevent cracking/breaking of the struts attached to the material left at the two ends of the stent pattern due to

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harmonic oscillations induced by the ultrasonic cleaner, a mandrel is placed down the center of the tube during the cleaning/scrap removal process. At completion of this process, the stent structure are rinsed in water. They are now ready for electropolishing.

Please enter the following substitute paragraph for the specification at page 18, line 16 as follows:

The stents are preferably electrochemically polished in an acidic aqueous solution such as a solution of ELECTRO-GLO#300, sold by ELECTRO-GLO Co., Inc. in Chicago, Ill., which is a mixture of sulfuric acid, carboxylic acids, phosphates, corrosion inhibitors and a biodegradable surface active agent. The bath temperature is maintained at about 110°-135° F (43°-57° C). and the current density is about 0.4 to about 1.5 amps per in.<sup>2</sup>. Cathode to anode area should be at least about two to one. The stents may be further treated if desired, for example by applying a biocompatible coating.

Please enter the following substitute paragraph for the specification at page 19, line 10 as follows:

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The stent of the present invention also can be made from metal alloys other than stainless steel, such as shape memory or superelastic alloys. Shape memory alloys are well known and include, but are not limited to titanium, tantalum, nickel titanium and